

25 June 2001

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Food and Drug Administration  
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Rockville, MD 20852

**SUBJECT: HV01/318**  
**Comments to: [Docket No. 01N-0191]**  
**Medical Devices; Global Harmonization Task Force; Study Group 1:**  
**Working Draft " Medical Devices Classification".**  
**Invasive Devices - Rule 5**

Gentlepersons:

Based upon our understanding of this rule, dental devices such as root canal posts, auxilliary retention pins, gutta percha root canal obturation material, including sealers; dentin/enamel restorative materials, i.e. resins/amalgams, gold and base metal alloys; dentin/enamel bonding agents; dentin cements; in short, all products for long term use in restorative dentistry would be considered Class B.

Dental implants, according to our reading of this rule, are also included in this class of devices and are Class B as well; to wit:

**"- ARE IN CLASS C IF THEY ARE INTENDED FOR LONG-TERM USE, EXCEPT IF THEY ARE USED IN THE ORAL CAVITY AS FAR AS THE PHARYNX, IN AN EAR CANAL UP TO THE EAR DRUM OR IN A NASAL CAVITY AND ARE NOT LIABLE TO BE ABSORBED BY THE MUCOUS MEMBRANE, IN WHICH CASE THEY ARE IN CLASS B."**

Please confirm if we are reading this correctly.

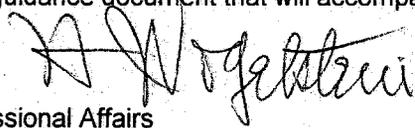
Our recommendation:

Additional clarification either in the rules, or via examples in a guidance document, would be most helpful.

Health Canada has recently published a most comprehensive list of medical devices with the respective Health Canada classification class.

You might want to consider the use of that document, either in it's present state or in a revised form, and incorporate it into a guidance document that will accompany the final subject document.

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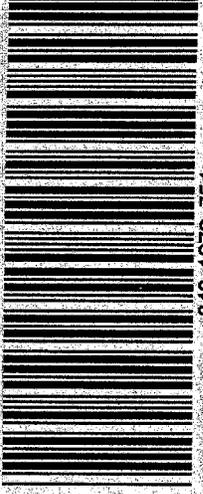
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